

ISO 9001:2015

“Risk Based Thinking”

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Purpose of presentation

Provide an overview of how the future ISO 9001:2015 standard addresses the topic of “risk”.

Revision presentation

- developed by the ISO subcommittee responsible for communication about the upcoming revisions to ISO 9001
- will be updated periodically as the revision progresses
- is available to anyone

What is “risk-based thinking”?

- risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001 – this revision makes it more explicit and builds it into the whole management system
- risk-based thinking is already part of the process approach
- risk-based thinking makes preventive action part of the routine
- risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk

**Where is risk addressed in
the current draft of
ISO 9001:2015?**

The main objectives of ISO 9001

- to provide confidence in the organization's ability to consistently provide customers with conforming goods and services
- To enhance customer satisfaction

The concept of “risk” in the context of ISO 9001 relates to the uncertainty in achieving these objectives

Risk in the clauses - Process Approach, Leadership, Planning

- in Clause 4 the organization is required to determine the risks which can affect its ability to meet these objectives
- in Clause 5 top management are required to commit to ensuring Clause 4 is followed
- in Clause 6 the organization is required to take action to address risks and opportunities

Risk in Clauses – Operation, Evaluation, Improvement

- Clause 8 - the organization is required to have processes which identify and address risk in its operations
- Clause 9 the organization is required to monitor, measure, analyse and evaluate the risks and opportunities
- In Clause 10 the organization is required to improve by responding to changes in risk

Why should I adopt “risk-based thinking”?

- to improve customer confidence and satisfaction
- to assure consistency of quality of goods and services
- to establish a proactive culture of prevention and improvement
- Successful companies intuitively take a risk-based approach

What should I do?

Use a risk-driven approach in your organizational processes

- **identify what the risks and opportunities are in your organization – it depends on context**
 - ISO 9001:2015 will not automatically require you to carry out a full, formal risk assessment, or to maintain a “risk register”
 - ISO 31000 (“Risk management — Principles and guidelines”) will be a useful reference (but not mandated)

What should I do? (continued)

- **analyse and prioritize the risks and opportunities in your organization**
 - *what is acceptable?*
 - *what is unacceptable?*
- **plan actions to address the risks**
 - *how can I avoid or eliminate the risk?*
 - *how can I mitigate the risk?*
- **implement the plan – *take action***
- **check the effectiveness of the actions – *does it work?***
- **learn from experience – *continual improvement***

What is next?

Additional updates and information will be made available as the revision process proceeds